IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	J. Christopher Flaherty et al.	Examiner: Witczak
Serial No.:	10/820,195	Group Art Unit: 3767
Filed:	April 6, 2004	Docket No.: INSL-0110CP
Title:	Data Collection Assembly for Patient Infusion System	
Conf. No.: 7413		

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Applicant has reviewed the Office Action mailed on February 13, 2006. Please amend the above-identified patent application as follows.

This response is accompanied by a Petition, as well as the appropriate fee, to obtain a 5-month extension of the period for responding to the Office action, thereby moving the deadline for response to August 13, 2006.

Amendments to the Claims are reflected in the listing of claims that begins on page 2 of this paper;

Remarks begin on page 10 of this paper.

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1 (original). A system for delivering fluid to a patient, comprising:

A) a fluid delivery device including,

an exit port assembly,

a dispenser for causing fluid from a reservoir to flow to the exit port assembly,

a local processor connected to the dispenser and programmed to cause fluid flow to the exit port assembly based upon flow instructions, and

a local communication element connected to the local processor;

B) a remote control device separate from the fluid delivery device and including,

a remote processor,

user interface components connected to the remote processor, and

a remote communication element connected to the remote processor and adapted to communicate with the local communication element of the fluid delivery device such that information can be transferred between the local processor and the remote processor; and

C) at least one data collection assembly adapted to at least one of measure, monitor, calculate, and store a physiologic parameter of a patient.

2 (original). The system of Claim 1 wherein the data collection assembly measures the physiologic parameter.

3 (original). The system of Claim 1 wherein the physiologic parameter is blood glucose.

4 (original). The system of Claim 1 wherein the data collection assembly measures the physiologic parameter from a physiologic sample.

5 (original). The system of Claim 4 wherein the physiologic sample is a bodily fluid.

6 (original). The system of Claim 5 wherein the bodily fluid is blood.

7 (original). The system of Claim 1 wherein the data collection assembly includes a sensor that measures the physiologic parameter.

8 (original). The system of Claim 7 wherein the sensor is remotely deployable with respect to the data collection assembly, and the data collection assembly communicates with the sensor.

9 (original). The system of Claim 8 wherein the data collection assembly also includes a sensor communication element providing communication with the remote sensor.

10 (original). The system of Claim 7 wherein the remote sensor is subcutaneously implantable in a patient.

11 (original). The system of Claim 7 wherein the remote sensor is adapted to be positioned on a skin surface of a patient.

10 (original). The system of Claim 7 wherein the sensor is adapted to measure the physiologic parameter from a sample removed from a patient.

11 (original). The system of Claim 10 wherein the sensor comprises a glucometer.

12 (original). The system of Claim 7 wherein the data collection assembly also includes a storage element adapted to store the measurements received from the remote sensor.

13 (original). The system of Claim 7 wherein the sensor utilizes light to perform measurement of the physiologic parameter.

14 (withdrawn). The system of Claim 7 wherein the data collection assembly includes a transcutaneous access tool in fluid communication with the sensor.

15 (withdrawn). The system of Claim 8 wherein the data collection assembly is in fluid communication with the sensor.

16 (original). The system of Claim 8 wherein the data collection assembly is in electrical communication with the sensor.

17 (original). The system of Claim 1 further including an alarm.

18 (original). The system of Claim 17 wherein the alarm provides an audible alert.

19 (original). The system of Claim 17 wherein the data collection assembly activates the alarm when a predetermined level of the physiologic parameter is reached.

20 (original). The system of Claim 19 wherein the physiologic parameter is blood glucose.

21 (original). The system of Claim 20 wherein the predetermined level comprises hypoglycemia.

22 (original). The system of Claim 1 wherein the data collection assembly is integrated into the fluid delivery device.

23 (withdrawn). The system of Claim 22 wherein the fluid delivery device includes another subcutaneous access tool in fluid communication with the data collection assembly.

24 (withdrawn). The system of Claim 23 wherein the fluid delivery device is adapted to perform the functions of a glucometer.

25 (original). The system of Claim 1 wherein the data collection assembly is integrated into the remote control device.

26 (original). The system of Claim 25 wherein the remote control device includes a subcutaneous access tool in fluid communication with the data collection assembly.

27 (original). The system of Claim 26 wherein the remote control device is adapted to perform the functions of a glucometer.

28 (original). The system of Claim 1 wherein the fluid delivery device comprises a disposable assembly and a reusable assembly.

29 (original). The system of Claim 28 wherein the disposable assembly includes the data collection assembly.

30 (withdrawn). The system of Claim 28 wherein the reusable assembly includes the data collection assembly.

31 (original). The system of Claim 1 wherein the remote control device comprises a personal data assistant.

32 (withdrawn). The system of Claim 1 wherein the data collection assembly is adapted to be worn on an arm of a patient.

33 (withdrawn). The system of Claim 1 wherein the exit port assembly of the fluid delivery device includes a transcutaneous access tool.

34 (withdrawn). The device of Claim 33 wherein the transcutaneous access tool comprises a needle.

35 (original). The system of Claim 1 wherein the communication between the remote control device and the fluid delivery device is wireless.

36 (original). The system of Claim 35 where the wireless communication is at least one of radio frequency and microwave signals.

37 (original). The system of Claim 35 where the wireless communication is at least one of infra-red and optical signals.

38 (original). The system of Claim 1 wherein at least one of the local processor and the remote processor are programmed to use information from the data collection assembly to calculate the flow instructions.

39 (original). The system of Claim 1 wherein information from the data collection assembly is used by at least one of the local processor and the remote processor to determine an alarm condition.

40 (original). The system of Claim 1 wherein information from the data collection assembly is used by at least one of the local processor and the remote processor to determine or monitor a variable of the flow instructions.

41 (original). The system of Claim 1 wherein the fluid delivery device delivers fluid only upon receiving a signal from the remote control device.

42 (withdrawn). The system of Claim 1 wherein the fluid delivery device further comprises projections having adhesive adapted to attach the fluid delivery device to a skin surface of a patient.

43 (withdrawn). The system of Claim 42 wherein the projections are unitary and extend from the fluid delivery device such that the fluid delivery device is positioned between the unitary projections and the skin surface.

44 (withdrawn). The system of Claim 42 wherein the exit port assembly of the fluid delivery device includes tubing secured to the skin surface by one of the projections.

45 (withdrawn). The system of Claim 44 wherein one projection includes a transcutaneous penetrating cannula connected to the tubing.

46 (withdrawn). The system of Claim 42 wherein the projections extend from opposing sides of the fluid delivery device.

47 (withdrawn). The system of Claim 42 wherein the projections extend from all sides of the fluid delivery device.

48 (withdrawn). The system of Claim 1, wherein the fluid delivery device further comprises a reservoir, and the dispenser controls fluid flow from the reservoir to the exit port assembly.

49 (original). The system of Claim 48, wherein the reservoir contains a therapeutic fluid.

50 (original). The system of Claim 49 wherein the fluid comprises insulin.

51 (withdrawn). The system of Claim 48, wherein the fluid delivery device further comprises a fill port connected to the reservoir.

52 (withdrawn). The system of Claim 48, wherein the reservoir is made of a flexible material and collapses as emptied.

53 (withdrawn). The system of Claim 52, wherein the reservoir is pressurized.

54 (withdrawn). The system of Claim 53, wherein the fluid delivery device further comprises a spring pressurizing the reservoir.

55 (withdrawn). The system of Claim 1 wherein:

the local processor of the fluid delivery device is programmed to cause a flow of fluid to the exit port assembly based solely on flow instructions from the separate, remote control device;

the local communication unit includes a wireless receiver for receiving the flow instructions and delivering the flow instructions to the local processor;

the remote communication unit of the remote control device includes a remote transmitter for sending the flow instructions to the local receiver; and

the user interface components of the remote control device include input components connected to the remote processor for allowing a user to enter the flow instructions.

56 (original). The system of Claim 55 wherein the fluid delivery device includes a housing containing the exit port assembly, the dispenser, the local processor, and the wireless receiver, and wherein the housing is free of user input components for providing the flow instructions to the local processor.

57 (original). The system of Claim 1 wherein:

the local processor of the fluid delivery device is programmed to provide flow information;

the local communication unit includes a wireless transmitter for transmitting the flow information from the local processor;

the remote communication unit of the remote control device includes a remote receiver for receiving the flow information from the local transmitter; and

the user interface components of the remote control device include output components connected to the remote processor for allowing a user to receive the flow information.

58 (original). The system of Claim 57 wherein the fluid delivery device includes a housing containing the exit port assembly, the dispenser, the local processor, and the local

communication unit, and wherein the housing is free of user output components for providing the flow information from the local processor to a user.

59 (original). The system of Claim 57 wherein:

the local processor is programmed to receive at least some of the flow instructions from the remote control unit;

the local communication unit also includes a wireless receiver connected to the local processor;

the remote communication unit of the remote control device includes a remote transmitter for sending the flow instructions to the local receiver; and

the user interface components of the remote control device include input components connected to the remote processor for allowing a user to enter the flow instructions.

60 (withdrawn). A kit including a system according to Claim 1, and further comprising a subcutaneous access tool for connection to the exit port assembly of the fluid delivery device.

61 (withdrawn). A kit according to Claim 60, including a single remote control device, a single data collection assembly, a plurality of fluid delivery devices, and a plurality of subcutaneous access tools.

62 (withdrawn). A kit according to Claim 61, wherein each fluid delivery device includes a bar code and the remote control device includes a bar code scanner.

63 (withdrawn). The system of Claim 1 wherein the fluid delivery device is packaged for shipping and handle prior to use in a container.

64 (withdrawn). The system of Claim 63 wherein the container and the fluid delivery device are arranged such that opening the container changes the electronic state of the fluid delivery device.

66 (withdrawn). The system of Claim 64 wherein opening the container connects a power supply of the fluid delivery device to the local processor of the fluid delivery device.

67 (withdrawn). The system of Claim 1, wherein the dispenser includes an expandable accumulator, an inlet valve controlling flow from a reservoir into the accumulator and an outlet valve controlling flow between the accumulator and the exit port assembly.

68 (withdrawn). The system of Claim 1, wherein the dispenser includes two expandable accumulators.

69 (original). The system of Claim 1, wherein the dispenser comprises a pump for pumping fluid from a reservoir to the exit port assembly.

70 (withdrawn). The system of Claim 1, further including at least one local sensor connected to the local processor and comprising at least one of an occlusion detector, a reservoir volume transducer, a reservoir empty detector, a leak detector, a pressure transducer, a fluid contact detector, an impedance monitor, a voltage detector, a photodetector, and a vibration monitor.

71 (withdrawn). The system of Claim 1, wherein the local processor includes programming which can be updated by the remote control device.

72 (withdrawn).The system of Claim 1, wherein the data collection assembly is adapted to communicate with a separate diagnostic device.

REMARKS

Applicant has carefully reviewed and considered the Restriction/Election Requirement mailed on February 13, 2006.

Applicant elects the following species: AVI: Embodiment in Figure 9; BIII: Embodiment in Figure 11; CII: Embodiment in Figure 14c; DI: Embodiment in Figures 1a-c. Applicant believes claims 1-13, 15-22, 25-29, 31, 35-41, 49, 50, 56-59 and 69 are readable thereon. Accordingly, applicant has withdrawn claims 14, 23, 24, 30, 32-34, 42-48, 51-55, 60-68 and 70-72.

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (781-457-4717) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 503188.

Date August 11, 2006

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